OCT 25 2001

K012769

ADMINISTRATIVE INFORMATION

Manufacturer Name:
MacroPore, Inc.
6740 Top Gun Street
San Diego, CA 92121

Official Contact:
Kenneth K. Kleinhenz
Director of Regulatory Affairs
Telephone (858) 458-0900
Fax (858) 458-0994

DEVICE NAME

Classification Name: Ear, nose, and throat synthetic polymer material

Trade/Proprietary Name: MacroPore *ENT* Reconstruction Film

ESTABLISHMENT REGISTRATION NUMBER

2031733

DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21CFR 874.3620, Ear, nose, and throat synthetic polymer materials are synthetic polymers intended to be implanted for use as a space-occupying substance in reconstructive surgery procedures of the head and neck. The device is intended to be shaped and formed by the surgeon to conform to the patient's needs. These devices are classified as Class II. Ear, nose, and throat synthetic polymer materials have been assigned Product Code NHB.

INTENDED USE

The MacroPore *ENT* Reconstruction Film is indicated for the following surgical applications:

1). Tympanic membrane repair.
2). Tympanoplasty in the middle ear.
3). Nasal splinting and surgical repair of nasal septum.
4). Guided tissue regeneration of the external ear.
5). Prevents adhesions between the septum and the nasal cavity

DEVICE DESCRIPTION

Design Characteristics

MacroPore *ENT* Reconstruction Film is a resorbable implant in sheet form manufactured from poly lactic acid (PLA). MacroPore *ENT* Reconstruction Film can be cut with scissors to the desired shape and size. The MacroPore Power Pen can also be used to cut or shape the MacroPore *ENT* Reconstruction Film to the desired shape or size.

MacroPore *ENT* Reconstruction Film Sheet is fully malleable when heated to approximately 55°C (for example, by the use of sterile hot water), and thus can be conformed three dimensionally to most any anatomical orientation. The MacroPore *ENT* Reconstruction Film can be rolled into a tube or used as a flat sheet. It can be used either alone or in conjunction with soft tissue fixation devices such as resorbable sutures, which also can serve to fixate the MacroPore *ENT* Reconstruction Film and prevent dislocation. The MacroPore *ENT* Reconstruction Film may be used in conjunction with various MacroPore manual instruments.

MacroPore *ENT* Reconstruction Film is provided in various shapes such as rectangles, ovals, and circles and will be provided in other shapes and sizes as needed for particular surgical procedures. MacroPore *ENT* Reconstruction Film is provided in sheets of 10mm x 10mm to 120mm x 120mm and will be provided in other shapes and sizes as needed for particular surgical procedures. The thickness of the MacroPore *ENT* Reconstruction Film ranges from 0.02 mm to 2.0 mm according to the region to be treated. The MacroPore *ENT* Reconstruction Film is provided with and without macroporous holes. The macroporous holes range in size from 50 microns to 3,000 microns in diameter and may be in aligned, offset, or random patterns. The borders of the sheets may be aligned with holes to attach suture material

Material Composition

The MacroPore *ENT* Reconstruction Film is fabricated from polylactic acid (PLA).

In Vitro Testing

Because the MacroPore *ENT* Reconstruction Film is intended to be heated in the surgical suite to temperatures above the material's glass transition temperature to facilitate shaping to anatomic structures, testing was performed to determine the effect of prolonged heating in saline at 60°C on inherent viscosity. The testing demonstrates that viscosity stayed within an appropriate range over 120 minutes. Therefore, the relatively brief exposure anticipated during the surgical preparation of MacroPore *ENT* Reconstruction Film is not expected to have a significant effect on its mechanical properties.

Aging testing was performed on MacroPore *ENT* Reconstruction Film. Testing demonstrated that the MacroPore *ENT* Reconstruction Film is strong enough for the indications for use.

Mechanical testing was performed on the MacroPore *ENT* Reconstruction Film which determined the MacroPore *ENT* Reconstruction Film to be substantially equivalent to the mechanical strengths of the predicate devices under indication for use conditions.

In Vivo Testing
An animal study was conducted to demonstrate safety and efficacy of the MacroPore *ENT* Reconstruction Film material. The animal studies demonstrated that the MacroPore *ENT* Reconstruction Film materials are appropriate for the indications for use.

EQUIVALENCE TO MARKETED PRODUCT

MacroPore *ENT* Reconstruction Film shares indications and design principles with the following predicate devices, which have been determined by FDA to be substantially equivalent to the following pre-amendment devices: Pillar Prolastic Sheeting, SupraFOIL, Seare Silicone Sheeting, Durasil I and Durasil II, Specialty Surgery Silicone Elastomer, Lactosorb Ethmoid Stent, and MacroPore Protego System.

Indications For Use
The MacroPore *ENT* Reconstruction Film shares identical indications for use principles with the predicate devices as both the MacroPore *ENT* Reconstruction Film and the predicate devices are indicated for the same surgical procedures.

Design and Materials
The physical designs of MacroPore *ENT* Reconstruction Film and the predicate devices Pillar Prolastic Sheeting, SupraFOIL, Seare Silicone Sheeting, Durasil I and Durasil II, Specialty Surgery Silicone Elastomer, Lactosorb Ethomoid Stent, and MacroPore Protego System) are substantially equivalent, consisting of a thin semi-rigid sheets that allow for contouring. Both the predicate devices and the MacroPore *ENT* Reconstruction Film have a semi-rigid construction. The MacroPore *ENT* Reconstruction Film and the predicates also share design features of allowing for contouring. The MacroPore *ENT* Reconstruction Film is fully contourable when heated to approximately 55°C. The thickness of the predicate devices and the MacroPore *ENT* Reconstruction Film are substantially equivalent as the MacroPore *ENT* Reconstruction Film thickness ranges are essentially a subset of the predicate ranges. The MacroPore *ENT* Reconstruction Film has a thickness range of .02mm – 2.0mm which is substantially equivalent to the predicate devices that range in thickness from .05mm – 2.0mm. The dimensions of the predicate device are also comparable to the MacroPore *ENT* Reconstruction Film as both devices are provided in rectangular sheets that are several centimeters in size. The mechanical characteristics of the MacroPore *ENT* Reconstruction Film are also substantially equivalent to the predicate devices. In addition to physical characteristics, both the predicate device and the MacroPore *ENT* Reconstruction Film can be cut to specific shapes and sizes by the end user.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2001

MacroPore, Inc.
c/o Kenneth K. Kleinhenz
Director of Regulatory Affairs
6740 Top Gun Street
San Diego, CA 92121

Re: K012769
Trade/Device Name: MicroPore ENT Reconstruction Film
Regulation Number: 21 CFR 874.3620; 21 CFR 874.4780
Regulation Name: Ear Nose and Throat Synthetic Polymer Material Intranasal Splint
Regulatory Class: Class II; Class I
Product Code: NHB; LYA
Dated: August 15, 2001
Received: August 17, 2001

Dear Mr. Kleinhenz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Indications for Use:
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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K012769